MARKED-UP COPY OF AMENDED CLAIMS:

84. (TWICE AMENDED) A transdermal delivery system ~~comprising~~ consisting essentially of a ~~blend of~~:

(a) one or more hydrophobic polymers; and

(b) a therapeutically effective amount of one or more drugs, at least one of which is of low molecular weight and liquid at or about room temperatures,

wherein said system is substantially free of water and liquids having a normal boiling point (i) below processing temperatures and (ii) equal to or greater than the normal boiling points of the low molecular weight drugs.

REMARKS

Applicants initially express their sincere appreciation for the courtesy extended to applicants' counsel during the personal interview conducted on July 3, 2001. During that interview, as reflected in the Examiner Interview Summary Record, agreement was reached with respect to claims 84 and 85. In particular, in view of the agreed-to amendment to claim 84, and based upon discussion of the prior art rejection over Horstmann *et al.*, it was agreed that this rejection has now been overcome. Applicants therefore respectfully submit that the present application is clearly in condition for allowance, and such action is respectfully solicited.

In the official action of July 12, 2000, claims 84 and 85 were rejected on two different bases. Claims 84 and 85 were thus rejected under 35 U.S.C. § 112, first paragraph, and under 35 U.S.C. § 102(b) over Horstmann *et al.* With respect to the rejection under § 112, the Examiner had taken the position that the claims directed to "hydrophobic" polymers are not supported in the specification, stating that the specification includes polymers which are not hydrophobic. In response, however, applicants have pointed out that, in the preferred embodiment of the present invention relating to highly plasticizing drugs, the specification does clearly express the need to use those specific adhesive formulations more restrictively defined in the specification; namely, the hydrophobic adhesives discussed therein. It is therefore respectfully submitted that claims 84 and 85, the latter being specifically directed to the most highly preferred acrylic-based adhesives for use therein, are each appropriately directed to these hydrophobic adhesives; that these claims fully comply with all of the requirements of § 112; and that, in accordance with the personal interview conducted on July 3, 2001, it is now clear that these claims are directed to patentable subject matter.

It is next noted that, in the advisory action of December 28, 2000, the Examiner had stated that applicants' claims are not directed to the highly plasticizing drugs discussed in applicants' prior response. It has been pointed out, however, that claim 84 does specifically require that the claimed system hereof include a low molecular weight drug which is a liquid at or about room temperatures. Therefore, these claims clearly do include these features which define these highly plasticizing drugs.

Turning to the rejection over Horstmann *et al.*, during the aforementioned personal interview, applicants' counsel discussed the disclosure of a transdermal therapeutic system in Horstmann *et al.* This disclosure relates to a layered structure including a matrix layer including a reactive substance, which is activatable, applied to a backing layer, and a separate layer controlling the access of cutaneous liquid. It is thus the matrix material of Horstmann *et al.* which comprises a basic material 15 which is permeable to water vapor, but substantially water insoluble, and which is required to be essentially free of active substances. The basic material, however, includes islands 14 distributed therein. These islands themselves consist of a solid pharmaceutical solution and a basic material which is water soluble or water swellable, and in which the matrix is activatable by cutaneous liquid. In this manner, controlled access of skin moisture into the matrix is effected, and the islands thus absorb moisture so that a system-controlled, intended supersaturation with active substance takes place, resulting in increased release of pharmaceutical (see col. 3, lns. 5-10). It is thus clear that the overall thrust of Horstmann *et al.* is in many respects directly contrary to that of the presently claimed invention. The present claims specifically call for a transdermal delivery system which consists essentially of hydrophobic polymers. These claims are therefore clearly

distinguishable from Horstmann *et al.*, which, to the contrary, requires moisture to be absorbed into the device, and thus requires that a hydrophilic material must be present in the base material of the islands 14 thereof. It is thus specifically stated in column 4, lines 10 *et seq.* of Horstmann *et al.* that various pharmaceutical auxiliaries are required, which are "swellable in water, such as, e.g., polyvinyl pyrrolidone, polyacrylic acid, polyvinyl alcohol, cellulose and its derivatives, naturally occurring slime formers, e.g., agar(agar), guar gum, and gum arabic, but as well inorganic materials such as kaolin or bentonite are suitable components for the base material of the islands (14, 24)." This specification then goes on to discuss the moisture absorption which occurs because of the presence of these materials creating supersaturation within the islands in order to precipitate the active substance thereof.

It is therefore clear, as recognized by the Examiner, that the amendment of claim 84 to require a transdermal delivery system "consisting essentially of" the listed components clearly distinguishes over Horstmann *et al.*, which requires the use of a hydrophilic adhesive material to draw moisture into the compositions thereof. It is further apparent that these claims clearly overcome the Examiner's contention that the "comprising" language does not exclude the water swelling polymers of Horstmann *et al.*

It is also noted that claim 84 specifically requires that the system be substantially free of water, while the system in Horstmann *et al.* is one which requires the absorption of skin moisture (water) in order to activate the compositions thereof. Again, the teachings of Horstmann *et al.* are directly contrary to those of the present application, and for this reason alone it is clear that the present claims are clearly patentable over the prior art, including Horstmann *et al.*

At this point applicants would again remind the Examiner that claim 84 was initially copied from International Application No. WO 96/40085. This application claims priority from pending U.S. Application No. 08/472,759, filed on June 7, 1995, and Application No. 08/578,308, filed on December 26, 1995. One or both of these applications or a continuation of same may well still be pending in the United States Patent and Trademark Office. It is therefore quite possible that, if this is the case, interfering subject matter exists between the present allowable claims 84 and 85 and such application. It is therefore once again requested that the Examiner consider these facts in connection with the allowability of claims 84 and 85.

It is therefore again respectfully submitted that claims 84 and 85 are now in condition for allowance, and such action is therefore respectfully solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any objections he might have to such allowance

Finally, if there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Respectfully submitted,

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